IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES LLC AND EDWARDS LIFESCIENCES PVT, INC.,	)	
Plaintiffs	)	
v.	)	C.A. No. 12-023-GMS
MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., MEDTRONIC VASCULAR GALWAY LTD., MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,	)	
Defendants.	)	

MEDTRONIC'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW PURSUANT TO FED. R. CIV. P. 50(b)

Pursuant to Federal Rule of Civil Procedure 50(b), defendants Medtronic CoreValve LLC, Medtronic CV Luxembourg S.A.R.L., Medtronic Vascular Galway Ltd., Medtronic Inc., and Medtronic Vascular, Inc. (collectively, "Medtronic") hereby renew their motion for judgment as a matter of law (the "Motion") for (1) no direct infringement; (2) no infringement under 35 U.S.C. § 271(f); (3) invalidity for non-enablement; (4) invalidity for failure to comply with the written description requirement; (5) invalidity for obviousness; (6) no willful infringement; and (7) failure to present sufficient evidence to sustain the damages verdict.

The grounds for Medtronic's Motion, as set in Medtronic's opening brief in support of the Motion, are as follows:

1. Edwards failed to present substantial evidence that the CoreValve product is "compressible to a compressed external diameter capable of being introduced through an 18 French arterial introducer and into a patient's vasculature using a catheterization technique." The

CoreValve can only be introduced using a catheterization technique through an arterial introducer that is 6.0 mm, and the claim requires an introducer that is 5.7 mm or less.

2. Edwards failed to present substantial evidence that the CoreValve frame "resists recoil" because the self-expanding frame of the CoreValve does not resist recoil. Edwards failed to present any evidence to show that any recoil is generated during the implantation of the CoreValve device.

3. Edwards failed to present substantial evidence to show that the shipment of pericardial sacs from the United States to Mexico infringes under §§ 271(f)(1) or (2). Undisputed evidence shows that the pericardial sac is not a component, Medtronic does not supply more than one "component" from the United States, the pericardial sac is not combined with the CoreValve product, and the pericardial sac is a commodity that is suitable for substantial non-infringing use.

4. Undisputed evidence shows that the patent neither discloses nor teaches how to make the claimed prosthetic valve frame such that it is "compressible to a compressed external diameter capable of being introduced through an 18 French arterial introducer and into a patient's vasculature using a catheterization technique" and has "sufficient radial strength to resist the recoil force exerted by the stenosed aortic valve." In addition, it does not enable the full scope of the claim.

5. Undisputed evidence shows that the patent lacks sufficient written description support for the limitation "providing the frame with sufficient radial strength to resist the recoil force exerted by the stenosed aortic valve" to the extent the asserted claims cover self-expanding valves. Undisputed evidence also shows that the patent lacks sufficient written description support for the limitation "the frame being compressible to a compressed external diameter capable of being introduced through an 18 French arterial introducer and into a patient's

vasculature using a catheterization technique" to the extent the asserted claims cover a device in which the frame only, without any tissue inside, is compressed and delivered through an introducer with a diameter of 5.7 mm or less into a patient's vasculature using a catheterization technique.

6. Undisputed evidence shows that the asserted claims are invalid as obvious over the asserted prior art.

7. There is insufficient evidence to support the verdict of willful infringement. Medtronic's defenses are objectively strong, and are further supported by Edwards' own admissions in foreign proceedings. In addition, Edwards presented no evidence that it was unreasonable for Medtronic to believe that the self-expanding Nitinol frame of the CoreValve device did not meet the elements of any valid claims of the '825 patent. The infringement verdict, by contrast, was based upon Edwards' infringement theory which the Court found "appears erroneous and misguided."

8. The damages verdict lacks substantial evidence because the lost profit award is based on sales by unnamed entities. In addition, the lost profits award is improperly based on a transfer price paid by unnamed entities which does not constitute lost profits. The damages verdict also lacks substantial evidence because it is based on conclusory testimony that Edwards could have made all of Medtronic's sales but for the alleged infringement. The damages verdict also lacks substantial evidence because it is based on sales of the CoreValve device that are exempt from infringement. Finally, the damages verdict lacks substantial evidence because it is based on the shipment of a raw material from the United States to Mexico which cannot constitute infringement as a matter of law.

/s/ David M. Fry

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